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CR – Civil Ri FNS Instruction 113-2	Civil Rights Compliance and Enforcement in the Special Supplemental Nutrition Program for Women, Infants and Children and the Commodi Supplemental Food Program	•
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94-WIC-56	Responding to Subpoenas and Search Warrants	in	GA:01.0	
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Policy No. AUT:04.0

Telephone with Data Communications Capabilities

Purpose

To ensure that data (issuance, inventory, appointments, transfers, and certification, etc.) can be passed between state agency (SA), local agency (LA) and clinic. To ensure SA access to LAs and clinics for remote maintenance and support.

Authority

State Policy

Policy

All LAs and clinics shall have access to a dedicated telephone line (compatible with the Bell 212A standard) hooked to a modem. This telephone line shall end in a standard RJ11C modular jack. The jack shall be located within 5 feet of workstation 01 (station with the modem attached).

Procedures

- I. All network and stand alone PCs shall have a dedicated modem line. No exceptions shall be made.
- II. All notebook computers (portables) shall attach to a phone line daily, initiate the call to the SA and transfer data. A dedicated modem line is not required for notebooks since they initiate the call to the SA. Access to a phone line and the ability to transfer data is required.
- III. The modem line shall be dedicated for data transmission. Agencies and clinics may not use the dedicated line for phone calls other than software and hardware support calls. Do not attach fax machines or toggle switches.

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Policy No. FD:16.0

Issuance of Medical Nutritional Products and Formulas*
Other than Enfamil with Iron, Enfamil LIPIL with Iron, Enfamil Prosobee, Enfamil ProSobee LIPIL and Enfamil LactoFree LIPIL

Purpose

To ensure participants receive the formulas and/or medical nutritional products, which meet their medical and/or nutritional needs.

Authority

7 CFR Part 246.10; State Policy

Policy

A prescription is required on any formula or medical nutritional product except Enfamil with Iron, Enfamil LIPIL with Iron, Enfamil LactoFree LIPIL, and Enfamil ProSobee and Enfamil ProSobee LIPIL. WIC participants requesting any formula or medical nutritional product other than these formulas shall have a documented medical need.

Definition

*The term "formula" will be used to represent all non-contract formula and medical nutritional products throughout this policy. Medical nutritional products are those nutrition products that are included in a medical treatment protocol, serve as a therapeutic agent for life and/or health maintenance, and/or are required to treat an identified medical condition.

"Approval Authority" refers to: certifying authority [refer to Policy CS:15.0 – this does not include WIC Certification Specialist (WCS)], registered dietitian, licensed dietitian, or nutritionist with a bachelor's or master's degree in human nutrition or dietetics, or community nutrition, or clinical nutrition, or home economics with a food and nutrition major (24 semester hours credit in human food and nutrition), or State Agency RD.

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Procedures

- I. Issuance of any formula other than Enfamil with Iron, Enfamil LIPIL with Iron, Enfamil LactoFree LIPIL, Enfamil ProSobee or Enfamil ProSobee LIPIL requires the following:
 - A. Required Documentation for Prescription
 - 1. A prescription from one of the following prescriptive authorities:
 - a. medical doctor (M.D.);
 - b. doctor of osteopathy (D.O.);
 - c. physician assistant (P.A.); or
 - d. nurse practitioner (N.P.).
 - 2. The written prescription shall contain the participant's name and the following information:
 - a. date of prescription;
 - b. name of formula;
 - c. length of issuance (number of months requested);
 - d. medical diagnosis for which the formula is indicated; and
 - e. signature of the prescriptive authority requesting the formula. Signature stamps are acceptable.
 - 3. Verbal prescriptions are acceptable, but shall be:
 - a. documented in the participant's record; and
 - b. followed up with a written prescription within two weeks. Facsimiles are acceptable.
 - 4. Incomplete written prescriptions shall be followed up with a phone call by the certifying authority (CA) to obtain any missing information, provided the prescription has the signature of the prescriptive authority; and the missing information shall be documented in the participant's record.
 - 5. When a formula has been prescribed, do not challenge with a different formula or issue a different formula

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without first obtaining approval from the health care provider who prescribed the formula. Note: The participant does not need to be challenged on contract formula prior to issuing a medically prescribed formula.

B. Requirements for Assessment:

- An assessment shall be performed on any participant prior to initial issuance of formula or when the approved length of issuance has expired. The following information shall be included in the assessment and considered for formula approval:
 - a. the medical diagnosis or condition(s) which necessitates the need for the formula;
 - b. the weight and length/height, which shall be plotted on the growth chart; measurements shall be no older than 7 days for an infant or 30 days for a child;
 - c. the pattern of growth over time, when previous measurements are available;
 - d. the diet recall and diet history (see Guidelines); and
 - e. an interview with the caregiver to determine if formula intolerance may be due to a feeding, preparation, or storage problem (refer to <u>Policy FD:13.0</u>).
- 2. Based on the assessment and the length of time requested on the prescription, the approval authority shall determine how long to issue formula and when a reassessment shall occur.
- 3. Special accommodations for an assessment shall be offered to families with special health care needs (refer to Policy CR:07.0).
- 4. When a growth problem is recognized during an assessment, e.g., weight loss or no weight gain, the participant's health care provider shall be notified (phone, fax, or letter) if the participant has not been assessed by that provider since the formula was last issued. This

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notification shall be documented in the participant's record. If the health care provider has assessed the participant it shall also be noted in the record.

- C. Requirement for Documentation in Participant's Record:
 - 1. Texas WIC Information Network (WIN) Documentation:
 - food package, formula code, and prescription expiration date shall be entered into the computer system according to instructions provided in the Texas WIN Reference Manual for Clinics and Local Agencies (LAs);
 - b. if using the formula code "999", documentation shall include formula name, quantity, (cans, packets, tetra packs, or bottles) and total price (refer to Policy FD:17.0).
 - 2. In addition to the prescription and assessment information, the following information shall also be documented:
 - a. the length of time the formula is to be issued, if different from what is on the prescription;
 - b. name of the appropriate LA or SA staff authorizing the formula; and
 - c. date the formula was issued.
- D. Requirement for Approval of Issuance:
 - 1. Qualified LA staff (as indicated in Section II of this policy) are required to approve the assigned level of formula. The state agency (SA) shall be called:
 - a. when qualified LA staff are not available or
 - b. for consultation purposes.
 - 2. SA approval is required for formula that is:
 - a. not listed in this policy;
 - not described in the guidelines issued by the SA; and/or

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- c. prescribed for reasons other than those listed in this policy.
- 3. In-State and Out-of-State Transfers
 - a. When a participant has been receiving a formula other than Enfamil with Iron, Enfamil LIPIL with Iron, Enfamil LactoFree LIPIL, Enfamil ProSobee or Enfamil ProSobee LIPIL because it was another state's contract formula, issue the appropriate comparable Texas contract formula.
 - b. When a transfer participant has been receiving a formula for medical reasons and does not have a prescription, issue that formula for only one month. Thereafter, a prescription shall be required from a health care provider.
- II. Formulas and Levels of Approval
 - A. Level I Formulas
 - Allowable Formulas
 Alsoy, Good Start, Follow
 Up, Follow-Up Soy, Similac
 with Iron, Similac Advance,
 Similac Lactose Free,
 Isomil Advance, Isomil

Reasons for Issuance Allergy or intolerance to contract formula, refer to <u>Policy FD:13.0</u> when issuing a milk based or soy based formula.

Isomil DF

Diarrhea due to gastrointestinal virus/infection or antibiotic usage (do not issue over 10 days) See II.A.3.b in this policy.

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Nutramigen	Allergy to milk and/or soy protein; infant with milk allergy is not required to be challenged on soy formula prior to issuance.
Alimentum (Powder)	Malabsorption and allergy or sensitivity to intact protein.
Alimentum RTU	Malabsorption, milk, soy and corn allergy or intolerance to Alimentum powder; Infant with milk allergy is not required to try soy formula prior to issuance.
Next Step Soy	Milk allergy in a child over one year of age.

- 2. Level I Approval Authority: Certifying Authority (CA)
- 3. Maximum length of issuance is:
 - a. one certification period for Nutramigen, Alimentum or Next Step Soy.
 - b. ten days for Isomil DF in conjunction with another formula the infant normally receives or as prescribed by the prescriptive authority.
 - c. all other Level I formulas require a reassessment every two or three months (to be determined by CA and coordinated with instrument issuance) to determine if the formula is still needed.

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В. Level II Formulas

Allowable Formulas Reason for Issuance 1.

> Pregestimil Malabsorption; allergy or

> > sensitivity to intact protein

with malabsorption.

Similac Low Iron; Diagnosed vitamin E **Enfamil Low Iron**

hemolytic anemia (0-3 months old), or

thalassemia major.

Enfamil AR Gastroesophageal reflux

disease (refer to Formula

Resource Book)

Contract formulas

concentrated to 22 and 24

calories per ounce (see Policy FD:13.0);

Enfamil 24 with Iron; Similac 24 with Iron

Increased calorie needs; volume restriction, inability to consume adequate volume

of standard formula. See II.B.4. in this policy.

EHMF (Enfamil Human

Milk Fortifier);

SHMF (Similac Human Milk Fortifier); Similac Natural Care Advance

Human milk fortifiers

See II.B.3.c. in this policy.

Enfamil Premature LIPIL

20 and 24 with Iron

Prematurity (do not issue if over 5.5 lbs). See

II.B.3.a. in this policy.

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> Similac Special Care Prematurity (do not issue

Advance 24 with Iron if over 8 lbs.) See II.B.3.a. in this policy.

Similac NeoSure Advance; Prematurity. See II.B.3.b. Enfamil EnfaCare LIPIL in this policy.

Similac PM 60/40 Renal, cardiac, or other

condition that requires lowered minerals.

Pediatric Formulas for Children Over One Year

All formulas with or with-For oral motor feeding out fiber: Pediasure, problems, tubefeeding or medical conditions which Pediasure Enteral, Compleat Pediatric, increase calorie needs. Kindercal, Kindercal TF, Puddings may be issued Nutren Junior, Resource to children with oral motor Just for Kids dysfunction.

Adult Formulas

NuBasics

Ensure, Ensure with Fiber, For oral motor feeding Ensure Plus, Ensure Pudding, Isocal, Osmolite, Nutren, Boost, Boost with Fiber, Boost Pudding, Resource, Compleat,

problems, tubefeeding, or medical conditions which increase calorie needs.

2. Level II Approval Authority: Registered dietitian, licensed dietitian, or nutritionist with a bachelor's or master's degree in human nutrition or dietetics, or community nutrition, or clinical nutrition, or home economics with a food and nutrition major (24

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semester hours credit in human food and nutrition), or SA approval.

- 3. Maximum length of issuance is one certification period with the following exceptions:
 - a. monthly for premature infant formulas, i.e., Enfamil
 Premature LIPIL and Similac Special Care Advance,
 so as not to exceed the safe weight limit;
 - b. **Similac NeoSure Advance** and **Enfamil EnfaCare LIPIL** may be issued using the following guidelines:
 - Infants with a birth weight of 4 lbs to 5 lbs 8oz (1801-2500 grams) may issue up to 3 months chronological age
 - ii. Infants with a birth weight of 3lbs 5oz to less than 4 lbs (1501- 1800 grams) may issue up to 6 months chronological age;
 - iii. Infants with a birth weight of 2lbs 10oz to less than 3lbs 5 oz (1201- 1500 grams) may issue up to 9 months chronological age; and/or
 - iv. Infants with a birth weight of less than or equal to 2 lbs 10oz (1200 grams) may issue up to 12 months chronological age.

Note: These are general guidelines. If prescribed for a longer length of time, contact SA staff.

c. Maximum length of issuance for Enfamil HMF, Similac HMF, or Similac Natural Care is one month.

Enfamil Human Milk Fortifier (EHMF) and **Similac Human Milk Fortifier** (SHMF) shall be discontinued when the infant reaches a maximum weight of 5½ pounds. A maximum of 25 packets/day is advised due to high mineral content. **Similac Natural Care Advance** can be issued until the infant weighs 8 pounds.

NOTE: Breastfeeding women shall not receive the enhanced breastfeeding food package when the infant is issued a human milk fortifier.

4. Standard Enfamil, Enfamil LIPIL, standard Similac, or Similac Advance, concentrated liquid or powder, shall be concentrated to

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yield 24 calories per ounce (see Guidelines), in lieu of issuing **Enfamil 24 with Iron** or **Similac 24 with Iron** ready-to-use, when the caregiver is physically and mentally capable. Refer to Policy FD:15.0 for clarification on the issuance of ready-to-use products. The prescriptive authority shall be contacted to explain WIC policy and to obtain approval to provide mixing instructions. The specific instructions that were given shall be documented in the participant's record. Note: These two formulas are <u>not</u> the premature formulas **Enfamil Premature LIPIL 24 with Iron** and **Similac Special Care Advance 24 with Iron**.

C. Level III Formulas

1. Allowable Formulas

Contract formulas concentrated to 27 and 30 calories per ounce (see Policy FD: 13.0)

Neocate Elecare

Reason for Issuance

Increased calorie needs; volume restriction, inability to consume adequate volume of standard formula

Severe malabsorption; allergy to intact protein and casein hydrolysates. Pregestimil, Alimentum or Nutramigen needs to have been tried prior to issuing Neocate or Elecare when prescribed for allergy.

Pediatric Formulas for Children Over One Year

Neocate One +, Neocate Junior, Peptamen Junior, Vivonex Pediatraic, Elecare, Pepdite One+ Severe malabsorption or allergy to intact proteins

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Adult Products

Vivonex, Vivonex Plus, Peptamen, Tolerex, Peptamen 1.5 Severe malabsorption

Metabolic Formulas

Metabolic Disorders

PKU Formulas

Phenylketonuria See C.4.

Phenex-1, Phenex-2, Lofenalac, Phenyl Free 2, Phenyl Free 2HP, PKU 1, PKU 2, PKU 3, XP Analog, XP Maximaid, XP Maxamum, Periflex, Phlexy-10 Drink Mix, PhenylAde Amino Acid Blend, PhenylAde MTE

- 2. Level III Approval Authority: LA registered dietitian, licensed dietitian, or SA approval.
- 3. Maximum length of issuance: one certification period.
- 4. **PKU formula** issuance requires a prescription from a metabolic center recognized by the Genetics Program at the Texas Department of Health. A sample prescription form and the issuance guidelines are provided in the appendix along with a list of the metabolic centers in Texas. WIC clinics are not to issue PKU formula unless the individual is being seen at a Metabolic Center. WIC clinic staff shall not provide diet counseling on the PKU diet.

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D. Level IV Formulas

1. Allowable Formulas

Reason for Issuance

MCT Oil, RCF (Ross Carbohydrate Free), Polycose, Moducal, Promod, Casec, Duocal

Ketogenic diet; failure to thrive secondary to underlying medical conditions; modular products for specific dietary treatments.

- 2. Level IV Approval Authority: SA approval.
- 3. Maximum length of issuance: one certification period.

III. Non-Compliant Issuance of Non-Contract Formulas

- A. LAs may be required to reimburse the SA for non-compliant issuance of non-contract formula as detected during the quality assurance review. The amount of reimbursement shall be calculated by the SA WIC office. Specifically, the food instruments in question shall be located and the dollar amount that was paid to the vendor for each card shall be recovered from the LA.
- B. Non-compliant issuance of non-contract formula includes any one of the following:
 - 1. lack of a written prescription by a M.D., D.O., P.A., N.P., incomplete prescription, or no documentation of a verbal prescription pending receipt of written prescription;
 - 2. a formula was issued to the participant past the length of issuance, as prescribed;
 - 3. there is no documentation in the participant's record:
 - a) of contract formula intolerance, or
 - b) that Enfamil with Iron, Enfamil LIPIL with Iron, Enfamil LactoFree LIPIL, Enfamil ProSobee or Enfamil

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ProSobee LIPIL is contraindicated by a medical diagnosis to substantiate the formula issuance;

- 4. the amount of formula issued exceeded the maximum allowable amount (see Guideline V in this policy); or
- 5. when the formula code "999" is used to issue formula for which a specific code exists, unless the code is used to issue a formula that exceeds the maximum price (refer to Policy FD:17.0), or a combination of formulas has been ordered, or the physician requests less than the maximum amount allowed.

Guidelines

- I. For SA approval of formula, contact the SA staff using the pager number: (512) 499-6814.
- II. Allergy or intolerance may be indicated by any of the following symptoms: vomiting, diarrhea, skin rash, bloody stools, weight loss or no weight gain, or respiratory conditions.
- III. A diet history includes questions about formulas and/or foods previously consumed with resulting reactions (the WIC diet history form WIC 42 and 42a may be used for obtaining this information but is not required).
- IV. **Enfamil 24 with Iron** or **Similac 24 with Iron** can be prepared from standard concentrated liquid or powdered Enfamil with Iron, Enfamil LIPIL with Iron or Similac Advance with Iron using the following directions:
 - A. three (3) scoops powder mixed with five (5) ounces of water; or
 - B. one (1) 13-ounce can of liquid concentrate mixed with 8½ ounces of water.

Written instructions to provide to the parent/guardian are located

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in the formula resource notebook under "Instructions for Concentrating Infant Formula". Also refer to <u>Policy FD:14.0</u>.

V. Maximum Issuance

Guide to Maximum Allowance per Month			
Maximum Amounts	Infant	Child/Woman	
Ready to Use	806 fl. oz.	910 fl. oz.	
Powdered	8 lb.	9 lb.	
Concentrate	403 fl. oz.	455 fl. oz.	

VI. For a more thorough listing of formulas, their description, indications, packaging and maximum allowed per month, refer to the WIC Formula Listing at http://www.tdh.state.tx.us/wichd/nut/formula-s.pdf.

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Issuance of Enfamil with Iron, Enfamil LIPIL with Iron, Enfamil ProSobee, Enfamil ProSobee LIPIL and Enfamil LactoFree LIPIL

Purpose

To ensure that all participants requiring milk-based, soy-based, or lactose-free formulas receive the standard contract formulas Enfamil with Iron, Enfamil LIPIL with Iron, Enfamil ProSobee, Enfamil ProSobee LIPIL or Enfamil LactoFree LIPIL. These standard contract formulas are nutritionally comparable to other non-contract brands of milk-based, soy-based and lactose-free formulas.

Authority

State Policy; 7CFR Part 246.7 10 (c)

Policy

Formula-fed infants and breastfed infants who receive supplemental formula shall be issued the contract formulas Enfamil with Iron, Enfamil LIPIL with Iron, Enfamil ProSobee, Enfamil ProSobee LIPIL or Enfamil LactoFree LIPIL, except when a different formula or medical nutrition product has been prescribed for a valid medical condition. Contract formula may also be issued to participants beyond one year of age for a valid medical reason.

Procedures

- I. Enfamil with Iron or Enfamil LIPIL with Iron shall be issued to infants unless:
 - A. the infant is already on Enfamil LactoFree LIPIL or Enfamil ProSobee or Enfamil ProSobee LIPIL and the parent/guardian wants to continue on this formula; or
 - B. the parent/caretaker wants the infant to try another contract formula for symptoms of colic, (e.g., gassiness, bloating and

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severe crying, usually in infants younger than three months), in which case counseling shall be provided on how to deal with colic. If, after counseling, the parent/caretaker still requests a formula change, offer the lactose-free formula, Enfamil LactoFree LIPIL, unless:

- 1. the family follows a strict vegetarian diet and requests the soy formula, Enfamil Prosobee or Enfamil ProSobee LIPIL;
- 2. there is a strong family preference for a soy formula; or
- 3. there is a prescription from the infant's healthcare provider of a documented valid medical need for:
 - a. a soy-based formula (e.g., galactosemia); or
 - b. a non-contract formula (refer to Policy FD:16.0).
- C. If intolerance to any of the standard contract formulas is reported, question the parent/caretaker to assess whether the symptoms of formula intolerance may be caused by errors in feeding, preparation or storage. If symptoms appear to be due to errors in feeding, preparation or storage, provide appropriate counseling, contact the healthcare provider for approval to continue issuing the contract formula.
- D. If parent/caretaker reports symptoms of diarrhea, bloody stools, vomiting, fever or if the infant has weight loss, poor or no weight gain, refer to the infant's healthcare provider. Document in the participant's record that this referral was made.
- II. Enfamil with Iron or Enfamil LIPIL with Iron concentrated to dilutions greater than the standard 20 calories per ounce:
 - A. Shall be issued in lieu of Enfamil 24 with Iron, ready-to-use when the caregiver is physically and mentally capable of mixing the formula (NOTE: Enfamil 24 with Iron is <u>not</u> the premature formula Enfamil Premature 24 LIPIL with Iron).
 - 1. Refer to <u>Policy FD:15.0</u> for the clarification on the issuance of ready-to-use products and <u>Policy FD:14.0</u> for the issuance of sample contract formula.
 - 2. Contact the prescriptive authority to explain WIC policy and to obtain approval to provide mixing instructions.

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- 3. Document the specific instructions that were provided in the participant's record.
- B. Requires a prescription, assessment, documentation and approval authority as described in Policy FD:16.0 only when:
 - 1. additional sample contract formula is provided (refer to Policy FD:14.0), or
 - 2. WIC staff provide instructions for concentrating the formula.
 - a. instructions can be provided with a verbal order (v.o.) in lieu of a written prescription. The v.o must be documented in the participant's chart and a follow-up written prescription is not required.
 - b. for concentrations to 22 and 24 calorie per ounce, approval authority is a Level II.
 - c. for concentrations to 27 and 30 calorie per ounce approval authority is a Level III.
- III. Issuance of contract formula to participants beyond one year of age:
 - A. Requires a prescription, assessment, documentation and approval authority as described in Policy FD:16.0:
 - 1. For issuance with a diagnosis of milk allergy, galactosemia, strict vegetarian diet (vegan) or premature infants needing contract formula up to corrected age of one year, approval authority is a Level I.
 - 2. For issuance with a diagnosis of developmental disability or delay, for premature infants beyond one year of corrected age or other medical reasons, approval authority is a Level III.
 - B. An additional 1/8 package of formula may be issued, if needed, to meet the needs of a participant beyond one year of age.

 Justification for this additional formula shall be determined and documented in the participant's record.

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Policy No. IM:07.0

Immunization Quality Assurance

Purpose

To maintain and verify that minimum standards and requirements consistent with the TDH Immunization Program are met by local agencies (LAs) who are contracted to provide on-site immunizations. To maintain and verify that all other LAs perform immunization screening and referral procedures as required by USDA.

Authority

Texas Department of Health (TDH) WIC Policy

Policy

Each LA shall be monitored by TDH Quality Assurance staff annually.

Procedures

- I. The following program areas shall be addressed:
 - A. monitoring tools;
 - B. pediatric guidelines; and
 - C. barriers to immunization delivery.
- II. Issues that are noted that represent a serious threat to health or safety shall result in immediate intervention by WIC or immunization personnel. The authorizing physician shall be notified immediately.
- III. All health and safety issues shall be documented in writing and provided to the LA WIC Director, LA immunization personnel and a copy sent to the state agency (SA) WIC Immunization Coordinator.

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- IV. Corrective action taken as a result of monitoring shall be documented and available for review.
- V. Educational opportunities and technical assistance shall be made available via local and regional Immunization Program personnel.
- VI. A self-audit shall be completed annually. Forms may be developed locally utilizing areas on the TDH Immunization Survey. Audit results shall be kept on file and made available during the LA immunization monitoring/review.